

**REMARKS**

Claims 1-8, 10 and 14 are pending. By the present amendment, claims 1 and 14 are amended. Support for the amendments to claims 1 and 14 may be found in the specification at, for example, page 43, lines 16-22, the paragraph spanning pages 71-72, and Examples 4 and 5.

No new matter has been added by way of the amendments.

**Rejections Under 35 U.S.C. § 112, First Paragraph**

Claims 1-8, 10 and 14 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. More specifically, the Office Action alleges that the recitation of “a tag protein that is benign to the plant or portion thereof when expressed” and “the coding region of interest which does not include an antibiotic resistance or herbicide resistance selection” in claim 1 adds new matter.

The Applicant respectfully submits that these phrases are not new matter and are supported in the specification at, for example, page 43, lines 16-22 or at the paragraph bridging pages 71-72. To expedite prosecution, however, claims 1 and 14, have been amended to delete the above-two phrases, and to recite that wherein the first, second, and third coding regions encode proteins that confer no adaptive advantage, are benign to the plant, and are not antibiotic resistant. Support for the amendments may be found in the specification at, for example, page 43, lines 16-22, the paragraph spanning pages 71-72, and Examples 4 and 5.

**Rejections Under 35 U.S.C. § 103(a)**

Claims 1-8, 10 and 14 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Fabijanski et al. in view of Mason et al. and Chou et al.

Claims 1 and 14 are the only independent claims under examination, and therefore this rejection will be addressed with respect to these claims only. The remaining claims at issue under this rejection are dependent claims and by definition subject to the limitations of claim 1.

The Applicant respectfully submits that, further to the Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in view of the Supreme Court Decision in KSR

International Co. v. Teleflex Inc. (72 Fed. Reg. 57,526 (Oct. 10, 2007), a proper rejection under 35 U.S.C. § 103 requires:

1. a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference;
2. a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately;
3. a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable; and
4. whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The Applicants respectfully submit that Fabijanski et al. do not meet this test. Fabijanski et al. teach management and control of crops with novel traits through expression of a trait in plants that is lethal without the full complement of recombinant DNA (col. 6, ll 5-8, 24-33; emphasis added) and disclose that their “novel genetic constructs impart no morphologically obvious or easily detectable phenotype to plants ...[but] ... comprise silent genes that are only expressed when an unintended sexual cross occurs [i.e., in plants which do not include the full complement of recombinant DNA], which results in expression of the lethal trait and the undesired plant cells are eliminated” (col. 6, ll 37-42; emphasis added). Furthermore, Fabijanski et al. disclose that the novel trait must be linked to the lethal gene to ensure “that the novel trait can not persist in related species by transfer through sexual crossing” (col 7, ll 35-37; emphasis added). While the elements identified by the Examiner as taught by Fabijanski et al., such a

conditional lethal gene or a selection step, may be individually present, the combination of these elements in the context of the teachings of Fabijanski et al. does not lead to the claimed invention. This is because Fabijanski et al. do not disclose a second nucleic acid sequence including a repressor and a coding region of interest and do not disclose a selection strategy that is benign to the plant. Rather, Fabijanski et al. teach away from the claimed method in their emphasis that any desirable trait is associated with a lethal gene.

Furthermore, Fabijanski et al. do not teach antibiotic resistance as an undesirable feature, as is presently claimed. Rather, the pCG-2 transformation vector (which contains the Oncogene 1 and 2 sequences) taught by Fabijanski et al. includes a kanamycin resistance gene (col. 32, ll 60-64). Accordingly, Fabijanski et al. do not disclose a selection strategy that is not based on antibiotic resistance. Rather, Fabijanski et al. teach away from such a strategy in their demonstration of selection using a kanamycin resistance gene.

The addition of Mason et al. and Chou et al. does not remedy the deficiencies of Fabijanski et al. More specifically, Mason et al. teach transgenic tobacco plants expressing the hepatitis B surface antigen under the control of CaMV 35S promoter, and Chou et al. teach the zinc finger gene from *agrobacterium*, *ros*, and repression of the *virC/D* and *ipt* genes by binding of *ros* to the conserved operator "ros box". However even if the hepatitis B surface antigen of Mason et al. and the *ros* operator of Chou et al. were combined with the genetic constructs taught by Fabijanski et al., a skilled person would still not arrive at the claimed invention without having recourse to the disclosure of the above-referenced application since, to make the combination, the skilled person would have to ignore the specific teachings of Fabijanski et al. that any desirable trait must be linked with a lethal gene and that antibiotic resistance is a suitable selection strategy. With respect, this is impermissible hindsight reconstruction.

Accordingly, the Applicants respectfully submit that much more than the simple combination of the cited references in a single prior art reference is required to arrive at the claimed invention and that the combination of Mason et al. and Chou et al. with Fabijanski et al. does not lead to the claimed invention, particularly in view of Fabijanski et al.'s teaching of the advantages of linking a lethal gene to a desirable new trait and endorsement of antibiotic resistance. The Applicants therefore respectfully request that this rejection be withdrawn.

### **Provisional Double Patenting**

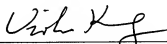
Claims 1-8, 10 and 14 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-24 of co-pending Application No. 10/719,996 in view of Mason et al., and over claims 18, 21 and 24 of co-pending Application No. 10/995,951 in view of Mason et al.

The Applicants thank the Examiner for the postponement of these rejections and confirm that they wish to continue to postpone the response to these rejections until the claims are otherwise determined to be allowable.

### **Conclusion**

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,



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